IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES ex rel. YOASH GOHIL,	:	
Plaintiff/Relator.	:	CIVIL ACTION
	:	No. 02-2964
v.	:	
	:	
SANOFI U.S. SERVICES INC. et al.,	:	
Defendants.	:	

July 21, 2020 **Anita B. Brody, J.**

MEMORANDUM

Relator Yoash Gohil brings this lawsuit against Aventis, a large pharmaceutical company and his former employer.[1] Among other things, Gohil alleges that Aventis violated the False Claims Act ("FCA") by engaging in a variety of nationwide kickback schemes between 1996-2004 to induce doctors to prescribe—and then request government reimbursement for— Aventis's cancer drug, Taxotere. One of the alleged schemes involves Aventis's reimbursement-assistance program, the "Providing Access to Cancer Therapy Program"

[1] As a result of several mergers, the Defendant has gone by several different names throughout the relevant period of this lawsuit. For ease of reference, the Court refers to Defendant solely as "Aventis."

("PACT").[2] PACT helped doctors submit reimbursement claims for Taxotere, handled administrative appeals when those claims were denied, and gave doctors free replacement vials of the drug when appeals were unsuccessful. Gohil maintains that these services were kickbacks that led to the submission of "false or fraudulent claims," in violation of the False Claims Act.

In June and July of 2019, both parties filed cross-motions for summary judgment focused on whether PACT's services were illegal kickbacks that gave rise to FCA liability. On March 4, 2020, I denied both motions. This memorandum explains that denial.[3]

[2] Throughout the relevant time period, Aventis hired third-party companies to operate the PACT Program. In this opinion, references to "PACT" should be taken to mean both Aventis and the companies it used to run PACT.

[3] Gohil also alleges that Aventis entered into a variety of separate kickback schemes to promote Taxotere, unrelated to the PACT Program. On April 24, 2020, Aventis filed a second summary judgment motion that, among other things, addresses those schemes. This memorandum does not address that motion, which remains pending.

I. Background[4]

A. Taxotere Enters the Market and Aventis Adopts Alleged Kickback Schemes.

Aventis's cancer drug, Taxotere, was first approved by the FDA in 1996. When it entered the market that year, Taxotere faced competitive disadvantages. Compared to its main competitor—a similar cancer drug called Taxol—Taxotere was more expensive and had been approved by the FDA for a fewer specific uses. According to Gohil, Aventis aimed to overcome these disadvantages by pursuing an aggressive Taxotere marketing scheme from 1996 to 2004. As part of this marketing plan, Gohil alleges, Aventis engaged in a number of separate kickback schemes designed to induce doctors to prescribe Taxotere instead of Taxol. One of those alleged schemes is Aventis's reimbursement-support program, PACT.

The Anti-Kickback Statute ("AKS") prohibits drug manufacturers from paying "kickbacks" to doctors with the purpose of influencing their decision to prescribe that manufacturer's drug.[5] This prohibition seeks to prevent arrangements that might cause doctors to make medical decisions for non-medical

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[4] This section is offered solely to provide context for the legal discussion that follows. For the most part, it outlines Gohil's narrative description of the facts, though the Court aims to rely on undisputed facts wherever possible. Aventis disputes many of Gohil's factual characterizations, and nothing in this section represents a factual finding by the Court.

[5] AKS violations can form the basis for civil liability under the False Claims Act. *See generally infra* Section III.

reasons. For example, if a drug company pays a doctor $1,000 to prescribe its drug and the doctor does so, there is a concern that the doctor made that decision for financial reasons that had nothing to do with the patient's best interest. *See United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015) ("The [AKS] . . . protect[s] patients from doctors whose medical judgments might be clouded by improper financial considerations").

Gohil alleges that the PACT Program worked in the same way. Taxotere is expensive, and doctors buy the drug ahead of time, before knowing whether they will get reimbursed. Aventis viewed reimbursement as critical to a doctor's decision to prescribe Taxotere. PACT provided free reimbursement assistance to doctors that purchased Taxotere—helping doctors submit reimbursement claims and pursue appeals when claims were denied. And when those appeals failed, PACT gave doctors free replacement drug. Like a $1,000 payoff, Gohil argues, these PACT benefits were designed to induce doctors to prescribe Taxotere for non-medical, financial reasons: namely, that choosing Taxotere may boost a doctor's chance of getting reimbursed and lower the administrative costs involved in the reimbursement process. Aventis, of course, disputes this argument.

B. Aventis viewed reimbursement as critical to a doctor's decision to prescribe Taxotere.

Taxotere is a "buy and bill drug." That means that doctors buy the drug from Aventis wholesalers, administer it to patients in their offices, then bill the

patient's insurer—including, when applicable, government healthcare programs—to be reimbursed for the cost of the drug and its administration. Because doctors buy Taxotere ahead of time, they face a financial risk if their claim for reimbursement is denied. For instance, assume that Doctor A buys $20,000 worth of Taxotere, out of her own pocket. She then treats Patient A with a $5,000 dose of Taxotere. She then submits a reimbursement claim to Patient A's insurer. If the insurer denies the claim, Doctor A stands to lose $5,000.

Aware of these financial risks, Aventis viewed a drug's reimbursement prospects as critical to a doctor's decision to prescribe that drug. In one internal report, Aventis recognized that doctors "will not" prescribe drugs like Taxotere unless they were "assured" that the drug would be reimbursed:

> Due to the high cost of chemotherapy and because office-based clinicians are "at risk" financially for the chemotherapy they administer, reimbursement has become a critical component to the success of new agents. Physicians will not utilize a product unless they will be assured that it will be paid for.

Relator's Ex. 7. Aventis also knew that doctors prescribing Taxotere sometimes had trouble getting reimbursed when they prescribed the drug for "off-label" uses—i.e., uses beyond those specifically approved by the FDA. *Id.*; Relator's Ex. 8 (Loreen Brown Dep.) at 109:6-17. And even for FDA-approved uses, Aventis knew that doctors may sometimes have trouble obtaining reimbursement—the reimbursement process could be time-consuming, highly technical, and fraught

with procedural pitfalls that could lead to claim denials.

C. Features of the PACT Program.

The PACT Program responded to these concerns.[6] Through PACT, Aventis hired dozens of "specialists" with expertise in reimbursement billing and coding. For any doctor who purchased Taxotere, these PACT specialists allegedly worked as a devoted support staff focused on securing reimbursement for Taxotere prescriptions.[7]

On the whole, the PACT Program had three main components. First, it helped doctors submit reimbursement claims for Taxotere. Second, it helped doctors appeal denied reimbursement claims. Finally, if a doctor lost an appeal,

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[6] Aventis created the PACT Program at some point prior to Taxotere's 1996 entrance into the market, but it is not clear when exactly it was first created. Once Taxotere received FDA approval, Aventis expanded PACT to cover Taxotere.

From 1996 to 2004, Aventis hired outside companies to run PACT, which both parties refer to as "third-party PACT vendors." Prior to 1996, State and Federal Associates, Inc. ("SFA") ran the PACT Program for Aventis. In 1996, SFA was acquired by Parexel, which ran PACT until 2002. In 2002, Aventis hired HealthBridge to administer the PACT Program, and renamed the program the "PACT+ Program." HealthBridge administered PACT through at least 2004.

[7] Neither party ever clearly explains whether these specialists worked directly for Aventis or, instead, worked for the third-party companies Aventis hired to run PACT. Some exhibits suggest the latter. *See, e.g.*, Relator Ex. 40 (HealthBridge employee stating that she worked on PACT for HealthBridge, describing Aventis as "our customer"). It does seem clear, though, that Aventis employed "PACT Reimbursement Managers" ("RMs"), who were Aventis employees that played a managerial role overseeing the PACT Program. One of those RMs was Loreen Brown, whose deposition testimony features prominently in both sides' briefing.

PACT provided the doctor an equivalent amount of free replacement drug.

1. *PACT helped doctors submit reimbursement claims.*

The PACT Program helped doctors submit claims for Taxotere reimbursement. The reimbursement process could be time-consuming and complicated, and claims sometimes failed for purely technical reasons.[8] PACT aimed to alleviate these problems. Among other things, PACT specialists provided billing and coding research for a given patient, and also performed "benefit verification" and "prior authorization" services—i.e., various inquiries to ensure that a patient had sufficient insurance coverage.

According to HealthBridge, the company Aventis hired to run PACT from 2002 to 2004, these services were intended in part to reduce a doctor's administrative costs by "outsourcing" reimbursement-related tasks to PACT specialists:

> [PACT] will do the work rather than instruct the physician office staff or patient in how to do the work. We believe that Aventis can create a **competitive advantage** with its customers by offering this level of service. . . . [P]hysician office staffs [will] appreciate the fact that this approach will relieve them of certain activities that divert their attention from patient care . . . .

Relator Ex. 15 (emphasis in original). An Aventis Reimbursement Manager made

[8] For instance, claims sent to Medicare were often denied as a result of a doctor's failure to use the correct type of "code" when making a submission. These claims had to follow two unique coding systems, and one mistake could lead to a denial.

a similar point, noting that he spoke to one doctor's office in Hawaii that:

> liked the fact that PACT+ did the [prior] authorization . . . . It is quite a bit of frustration for [the office-administrator's] personnel to sit on hold with the carrier in order to get the pre-authorization number. . . . [H]e had me meet his billing manager . . . [who] was very impressed . . . . [T]he fact that she would not have to spend the time following up on the authorization request was very important to her.

Relator Ex. 84. PACT provided these services for free.

2. *PACT helped doctors appeal denied reimbursement claims.*

The PACT Program also helped doctors pursue appeals when insurers denied their claims for Taxotere reimbursement. PACT specialists drafted model appeal letters for doctors and submitted appeal letters on their behalf. These appeals sometimes turned on why a doctor deemed an off-label use of Taxotere "medically necessary," and PACT specialists wrote letters addressing that question. PACT specialists also represented doctors at every level of an administrative appeal. This included telephonic "Fair Hearings" with Medicare carriers and, if those failed, appeal hearings in front of administrative law judges. These services were free for any doctor who purchased Taxotere.

A 2003 internal report explained that these appeal services provided the same "administrative outsourcing" benefit as PACT's claim-submission services: "PACT+ understands that offices are bogged down and under staffed as far as administrative duties are concerned. . . . By conducting this [appeal-related] work PACT+ has taken the authoring stage out of the mix for offices, which at times can

make an office become non-[compliant], . . . based on those inundating administrative tasks that take so long." Relator Ex. 41.

When writing appeal letters, PACT specialists identified themselves by their position with PACT and Aventis. *See, e.g.*, Aventis Ex. NNN (sample appeal letter opening with: "On behalf of Dr. [*Physician Name*], the Enhanced Aventis Oncology PACT Program is submitting a formal appeal . . . ."); *id.* (sample appeal letter signed by PACT specialist, with a signature block noting the specialist's position at "The Enhanced Aventis Oncology PACT Program.").

3. *PACT gave doctors replacement drug when their claims were denied.*

When doctors lost their claim appeals, PACT gave them free replacement drug. PACT replaced any quantity of the drug for up to a three-month course of treatment. For instance, assume Doctor A purchases $20,000 worth of Taxotere. She then treats Patient A with a $5,000 dose of the drug. Doctor A submits a claim for reimbursement to Medicare, the claim is denied, and Doctor A loses her appeals of that denial. Without PACT, Doctor A stands to lose $5,000. But through PACT, Doctor A instead receives $5,000 worth of new Taxotere at no new charge.

Gohil says that Aventis used this replacement-drug feature as a functional reimbursement guarantee. In response, Aventis says that its sales representatives were not allowed to make reimbursement guarantees to doctors. Several exhibits

in the record support Gohil's position. *See, e.g.*, Relator's Ex. 51 (Aventis sales rep describing how she convinced a hesitant doctor's office to prescribe Taxotere by promising that if reimbursement failed, "the WORST thing that would happen is we would replace the Taxotere").[9]

Aventis also had a policy requiring doctors to pay for replacement drug if they later received reimbursement, but internal emails suggest that Aventis never enforced this policy. *See, e.g.*, Relator's Ex. 104 (PACT Manager Loreen Brown writing in an email that Aventis "[n]ever really enforced this 'rule,'" and that Aventis did not "need to track [down]" specific doctors who may have received replacement product and later received reimbursement); Ex. 56 (Brown stating, in another email, that Aventis can only provide doctors replacement drug for denied claims, adding that this policy avoids giving doctors with "too much reimbursement" and "keep[s] the office from being accused of fraud.").

[9] *See also* Relator's Ex. 52 (PACT manager directing Aventis/PACT employee to tell a medical provider that "if [claim] appeals are denied, PACT+ will assist them in providing replacement drug"); Ex. 56 (sales-rep reporting that he told a solo-practice doctor—a "valued customer" "always looking to maximize her revenue and reimb[ursement,]"—that "if [she was] denied and appealed a claim properly . . . we could then replace the drug"); Ex. 55 (sales-rep telling her sales manager that a certain doctor was "using more and more taxotere" and asking what she could do to "keep him happy," and sales manager responding that if PACT's services do not "work, I will make sure we send him replacement drug"). *But see* Aventis Ex. I (Brown Dep.) at 311:8-18 (PACT Manager Loreen Brown denying that sales reps were allowed to tell doctors about the replacement-guarantee).

D. The Purposes of the PACT Program.

The parties, of course, dispute the goals behind the PACT Program. Gohil paints PACT, in essence, as a sales tool designed to get doctors to prescribe Taxotere over a competitor-drug like Taxol. Aventis says that PACT was solely intended to help patients. Gohil submits several pieces of evidence to support his position, including the following:

- An internal HealthBridge document stating that PACT's goals were to "maximize product sales revenue," "increase the physician's incentive to prescribe," and "gain a competitive advantage in the marketplace." Relator Ex. 15.[10]

- Several internal emails where Aventis employees discuss how they can use PACT to "differentiate" Taxotere from competitors like Taxol in order to boost Taxotere sales. [11]

- The fact that PACT Reimbursement Managers reported to Aventis's sales and marketing departments, received bonuses based in part on sales figures, and received performance evaluations that listed "Grow[ing] Current Business" as a "Key

[10] This document was a proposal that HealthBridge submitted to Aventis in January 2002 as part of its bid to become the next company to run PACT—which, at that time, was administered by Parexel. Shortly afterward, Aventis hired HealthBridge, and never appears to have objected to anything in the proposal. Relator Ex. 93 (Brown Dep.) at 226:16-20, 227:12-16.

[11] For instance, in one email chain, a regional sales manager described PACT's successful reimbursement efforts as "strategic items that clearly fit our differentiation message," signing the email with: "Good $elling, Greg." Aventis's director of marketing responds by stating that "Greg[] hits the nail on the head with the 'differentiation' message." Relator Ex. 86. Later, in a deposition, PACT Manager Loreen Brown explained that the "differentiation message" in this thread referred to the "sales teams . . . differentiating their product [Taxotere] versus Taxol." Ex. 93 (Brown Dep.) at 59:14-16, 254:4-5, 255:7-21.

> Goal." Relator's Ex. 6 (Hayes Dep.) at 33:22-34:1; Ex. 8 (Brown Dep.) at 41:4-13, 99:8-15; Ex. 90 (Brown's performance review).

In response, Aventis cites various statements in emails, depositions, and internal policy documents that say that PACT was solely meant to help patients access Taxotere. *See, e.g.*, Aventis Ex. I (Brown Dep) at 465:1-4 (denying that one of PACT's purposes was to help increase sales); *id.* at 228:21-229:7 (stating that PACT's goal was to ensure that patients with coverage received Taxotere).

II. Standard of Review

Aventis and Gohil both moved for partial summary judgment under Rule 56 of the Federal Rules of Civil Procedure.

Under Rule 56, summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" if it "might affect the outcome of the suit under the governing law . . . ." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual dispute is "genuine" if the evidence would permit a reasonable jury to return a verdict for the nonmoving party. *Id.* In ruling on a motion for summary judgment, the court must draw all inferences from the facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

The summary judgment standard is the same for cross-motions as it is when only one party moves for summary judgment. *Auto-Owners Ins. Co. v. Stevens &*

Ricci Inc., 835 F.3d 388, 402 (3d Cir. 2016). When facing cross-motions for summary judgment, the "court must rule on each party's motion on an individual and separate basis, determining, for each side, whether judgment may be entered in accordance with the Rule 56 standard." *Id.* (citations and internal quotation marks omitted). "Both motions must be denied if the court finds that there is a genuine dispute of material fact." 10A CHARLES ALAN WRIGHT & ARTHUR R. MILLER, ET AL., FEDERAL PRACTICE & PROCEDURE § 2720 (4th ed. 2020). In short, the ultimate question at summary judgment is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson*, 477 U.S. at 251-52.

Aventis can prevail on its motion by showing that Gohil lacks evidentiary support as to any of the elements necessary to prove his FCA claim at trial. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986) ("[T]he burden on the moving party may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case."). Gohil can survive Aventis's motion by showing that he has sufficient evidence to allow a jury to rule in his favor on every FCA element.

Gohil has a tougher task on his motion for summary judgment. For Gohil to prevail, he must affirmatively prove that (1) he has evidentiary support for *each* element of his FCA claim and (2) on *each* of those elements, the evidence is so

one-sided that no reasonable jury could rule in Aventis's favor.[12] To survive Gohil's motion, Aventis need only raise a genuine dispute of material fact as to *any one* of the FCA's elements.

[12] "Where the party moving for summary judgment is the plaintiff, or the party who bears the burden of proof at trial, the standard is more stringent." *Nat. State Bank v. Fed. Reserve Bank of New York*, 979 F.2d 1579, 1582 (3d Cir. 1992). When the moving party "has the burden of proof at trial, that party must show *affirmatively* the absence of a genuine issue of material fact: it . . . must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." *In re Bressman*, 327 F.3d 229, 238 (3d Cir. 2003) (quoting *United States v. Four Parcels of Real Prop.*, 941 F.2d 1428, 1438 (11th Cir. 1991); *see also* 10A WRIGHT & MILLER, ET AL., FEDERAL PRACTICE & PROCEDURE § 2727.1 ("[I]f the movant bears the burden of proof on a claim at trial, then its burden of production is greater. It must lay out the elements of its claim, citing the facts it believes satisfies those elements, and demonstrating why the record is so one-sided as to rule out the prospect of the nonmovant prevailing.").

III. Discussion

The FCA provides private citizens, called "relators," the ability to bring *qui tam* lawsuits on behalf of the government to recover civil damages against defendants who submit (or cause the submission of) "false or fraudulent claims" for payment from the government. Gohil brings FCA claims against Aventis under the FCA provisions that impose civil liability on anyone who "knowingly presents, or causes to be presented . . . a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1), or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," 31 U.S.C. § 3729(a)(2).[13]

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[13] Congress amended the FCA in 2009 when it passed the Fraud Enforcement and Recovery Act ("FERA"). FERA slightly changed the FCA's codification: prior to 2009, these two sections were codified §§ 3729(a)(1) and 3729(a)(2). After 2009, they are now codified as §§ 3729(a)(1)(A) and § 3729(a)(1)(B), respectively. To avoid confusion, the Court uses only the pre-2009 codification.

For the most part, the 2009 FERA amendments only apply to "conduct on or after" May 20, 2009. Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 § 4(f)(1), 123 Stat. 1617, 1625 (2009). But FERA has a retroactivity provision that applies to § 3729(a)(2). *Id.* FERA provides that the 2009 amendment to § 3729(a)(2) applies to "all claims under [the FCA] that are pending on or after" June 7, 2008. *Id.* This retroactivity provision does not apply to § 3729(a)(1).

Therefore, "both the pre-FERA and [post-]FERA versions of the False Claims Act apply in our case." *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 n.5 (3d Cir. 2018). For § 3729(a)(1), the pre-2009 version applies, because all of the conduct in this case took place prior to 2009. For § 3729(a)(2), the post-2009 version applies, because the FCA claims at issue in this case were pending after June 7, 2008. *See also* Mem. Op. at 21-22 (ECF No. 125) (Mar. 30,

Relators bringing FCA claims must satisfy four elements: (1) falsity; (2) causation; (3) knowledge; and (4) materiality. *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 487 (3d Cir. 2017). Gohil has produced enough evidence under each element to allow a jury to rule in his favor. Gohil's evidence, however, is not so one-sided as to warrant granting summary judgment in his favor, and there are genuine disputes of material fact as to several of the FCA elements. Therefore, I denied both parties' cross-motions for summary judgment.

A. Falsity

The first element in the FCA analysis is falsity. There are two kinds of "falsity" that are actionable under the FCA: "factual falsity" and "legal falsity." *United States ex rel. Druding v. Care Alternatives, Inc.*, 952 F.3d 89, 96 (3d Cir. 2020). A claim is "factually false" if the claimant "misrepresents what goods or services that it provided to the Government." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). A claim is "legally false when the claimant lies about its compliance with a statutory, regulatory, or contractual requirement." *Greenfield*, 880 F.3d at 94 (3d Cir. 2018). Gohil advances only a "legal falsity" theory, arguing that PACT's services are kickbacks that violate the AKS. Claims tainted by AKS violations are automatically "false"

2015) (Stengel, C.J.) (reaching same conclusion in opinion addressing Aventis's motion to dismiss Gohil's Second Amended Complaint). I recite the applicable versions of each provision in the body text above.

under the FCA. *See id.* at 95.[14] Therefore, if the PACT Program violated the AKS, then any claims submitted through PACT are "false" under the FCA.

The AKS is a criminal felony statute. Relevant here, it prohibits "knowingly and willfully" offering or paying any "remuneration" to induce prescriptions that may later be paid for under a federal health care program. 42 U.S.C. § 1320a-7b(b). To establish an AKS violation, Gohil must satisfy three elements. He must prove that (1) the PACT Program was "remuneration;" (2) at least one purpose of PACT was to "induce" doctors to prescribe more Taxotere; and (3) Aventis behaved "knowingly and willfully."

Genuine disputes of material fact exist for each element. Gohil points to sufficient evidence to allow a jury to conclude that: (1) PACT's replacement-drug feature worked as a functional reimbursement guarantee and was therefore "remuneration"; (2) at least one purpose of PACT was to induce more Taxotere prescriptions; and (3) Aventis knew that replacement-drug features like PACT's may violate the AKS and thus behaved "knowingly and willfully." But Aventis produces just enough countervailing evidence to send each of these issues to a jury.

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[14] In 2010, Congress amended the AKS to provide that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g). This amendment "clarified, but did not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the False Claims Act." *Greenfield*, 880 F.3d at 95 (internal quotation marks and brackets omitted).

1. Remuneration

There is a genuine dispute as to whether PACT's services constitute "remuneration" under the AKS. The AKS defines "remuneration" to include "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6). Courts generally interpret the term "remuneration" "expansively to include 'anything of value in any form whatsoever.'" *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 805 (S.D.N.Y. 2017), *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018).

The Office of the Inspector General for the Department of Health and Human Services ("OIG") has issued administrative guidance addressing when pharmaceutical-based reimbursement support services like PACT constitute "remuneration" under the AKS.[15] The OIG observes that pharmaceutical companies often offer support services in connection with the sale of their products, including "billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735, 2003 WL 2010428 (May 5, 2003)

[15] Of course, this guidance is not binding. But several courts have looked to this guidance as persuasive when evaluating whether reimbursement-support services violate the AKS. *See, e.g.*, *United States ex rel. Suarez v. AbbVie, Inc.*, 2019 WL 4749967, at *6 (N.D. Ill., Sep. 30, 2019); *United States ex rel. Forney v. Medtronic, Inc.*, 2017 WL 2653568, at *4 n.2 (E.D. Pa. June 19, 2017).

("2003 OIG Guidance"). The key question, in the eyes of the OIG, is whether these services have "substantial independent value," i.e., a value separate from that provided through the pharmaceutical product itself.

The answer is usually "no" when the services in question are limited to information-based administrative support tied a specific product. *Id.*; *see also* OIG Advisory Op. 00-10, at 7 (Dec. 15, 2000) (recognizing that drug manufacturers often "serv[e] as a clearinghouse for information regarding insurance coverage criteria and reimbursement levels for their products," and concluding that "these services have no substantial independent value"). The rationale is that these services have no independent value separate from the purchased product itself, and can be considered "part of the product[] purchased" such that their "cost is already included in the products' price." *Id*. But on the other hand, "if goods or services provided by [a] manufacturer eliminate an expense that the physician would have otherwise incurred," they may "have independent value to the physician." 2003 OIG Guidance, 2003 WL 2010428, at *23737.

Likewise, a limited reimbursement support system may raise kickback concerns if it is coupled with a "reimbursement guarantee that eliminates normal financial risks." *Id.* at *23735. For instance, "the anti-kickback statute would be implicated if a manufacturer were to couple a reimbursement support service with a promise that a purchaser will pay for ordered products only if the purchaser is

reimbursed by a federal health care program." *Id.* Replacement-drug programs can constitute this sort of reimbursement guarantee. *See* OIG Advisory Op. 00-10, at 7 (concluding that a pharmaceutical company's replacement-drug system—which offered doctors replacement drug if their reimbursement claims were denied—amounted to a reimbursement guarantee that "implicates the [AKS]"); *id.* (noting that the company's replacement-drug feature "confer[s] an independent financial benefit upon referring physicians by shifting the financial risk of unanticipated delays and denials associated with obtaining third party payor reimbursement from the prescribing physicians to the [drug manufacturer.]").

Here, a reasonable jury could certainly conclude that PACT's replacement drug program functioned as a reimbursement guarantee that implicates the AKS. The PACT Program provided doctors with free replacement vials of Taxotere as long as the doctor received a claim denial and exhausted some level of administrative appeal. A jury could surely find that this system worked as a functional reimbursement guarantee: if the doctor's claim was denied, the doctor would be "made whole" through free replacement drug.

Further, Gohil points to compelling evidence that, if credited by a jury, would support the inference that Aventis's sales force actively marketed this replacement-drug feature to doctors as a guarantee that participation in the PACT Program would eliminate reimbursement-related financial risk:

- In one email, an Aventis sales-rep describes how she convinced a hesitant doctor to prescribe Taxotere by promising that if reimbursement failed, "the WORST thing that would happen is we would replace the Taxotere." Relator Ex. 51.

- In another email, PACT Manager Loreen Brown told a sales-rep to tell a medical provider inquiring about Taxotere that "if [claim] appeals are denied, PACT+ will assist them in providing replacement drug." Relator Ex. 52.

- In another email chain, an Aventis sales manager sent an email describing a solo-practice doctor who "is always looking to maximize her revenue and reimb[ursement]." The sales-rep reports telling the doctor, a "valued customer," that "if [she was] denied and appealed a claim properly and was denied we could then replace the drug." Relator Ex. 56.

- Finally, in one email thread, a sales-rep forwards to a PACT employee a doctor's email asking about reimbursement for Taxotere. The sales-rep notes that the doctor "is using more and more taxotere," and asks if there is "anything we can do for this patient of his, I really want to keep him happy." The PACT employee responds that "I would like to see us go through PACT first," but adds that "[i]f that doesn't work, I will make sure we send him replacement drug." Relator's Ex. 55.

A jury could find that these promises of replacement-drug are precisely the sort of reimbursement guarantees that the OIG views as "remuneration" under the AKS.

Aventis disputes Gohil's position, argues PACT never provided physicians with a reimbursement guarantee, and cites (among other evidence) deposition testimony from Loreen Brown that sales representatives were not supposed to talk to doctors about reimbursement guarantees. *See* Aventis Ex. I (Brown Deposition) at 310:18-311:19. While several exhibits seems to contradict this testimony, it will

be up to the jury to decide which account to credit. Aventis also points out that doctors who received *partial* reimbursement payment for Taxotere would not receive replacement drug, which suggests that in at least some situations, PACT did not always guarantee a 100% reimbursement. *See* Relator's Ex. 56.

Ultimately, even though Gohil's evidence of remuneration is quite strong, Aventis's responses create a factual dispute that the jury must resolve.

2. "One Purpose to Induce"

The second element of the AKS looks at the purpose behind the remuneration offered. This element is satisfied if at least one purpose of the remuneration is to induce prescriptions or referrals. *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985). Relator does not have to prove that this is the "sole purpose" of the remuneration, and it is irrelevant if the remuneration has another, more benign purpose. *See Wood*, 246 F. Supp. 3d at 806; *see also Forney*, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017) ("[A]n AKS violation occurs even where only one purpose of the remuneration is to induce providers to use the defendant's products or services in the future." (citing *Greber* at 72)).

Gohil provides compelling evidence that one purpose of PACT was to induce doctors to prescribe more Taxotere. To start, one internal document from HealthBridge, the company Aventis hired to run PACT from 2002 to 2004, explicitly describes PACT's goals as "maximiz[ing] product sales," creating a

"competitive advantage," and "increas[ing] a physician's incentive to prescribe." Relator Ex. 15; *see also id.* ("[PACT] allows physicians to redeploy their staff members from paperwork and payer calls to patient care. In a competitive oncology market, this level of service can distinguish a product and increase the physician's incentive to prescribe." (emphasis in original)).[16]

Gohil also points to several emails that tend to show that at least one purpose of PACT was to boost sales by "differentiating" Taxotere from its competitor-drug, Taxol. In one email thread, a regional sales manager describes PACT's recent successful reimbursement efforts as "strategic items that clearly fit our differentiation message," signing the email with "Good $elling, Greg." Relator Ex. 86. Aventis's director of marketing responds by stating that "Greg[] hits the nail

[16] These statements came from a January 2002 proposal that HealthBridge sent Aventis, in an effort to persuade Aventis to hire HealthBridge to become the next company to run PACT. At the time, another company, Parexel, ran PACT. Shortly after receiving the proposal, Aventis hired HealthBridge, and nothing in the record suggests that Aventis raised any objections to anything in the proposal. *See* Relator's Ex. 93 (Brown Dep.) at 226:16-20, 227:12-16, 230:8-18, 231:22-24, 233:14-18 (PACT Manager Loreen Brown testifying, on behalf of Aventis and in a corporate capacity, that she did not recall anyone objecting to the proposal).

In response to this piece of evidence, Aventis says that the document reflects only HealthBridge's intent, but not that of Aventis. But Aventis never argues that the document is inadmissible or improper to consider at summary judgment. Rather, Aventis's argument goes to the persuasive weight of the evidence, which makes it an argument best suited for a jury to assess. At this stage, the document—if credited by a jury—strongly supports a conclusion that PACT was intended to incentivize doctors to prescribe more Taxotere.

on the head with the 'differentiation' message." *Id.* In her deposition, PACT Manager Loreen Brown—who was also on this thread—explained that the "differentiation message" referenced on the thread was the "sales teams . . . differentiating their product [Taxotere] versus Taxol." Ex. 93 (Brown Dep.) at 59:14-16, 255:7-21. In another email, an Aventis employee asks a PACT Manager for "ammunition to debunk" a doctor's suggestion that his colleagues prescribe Taxol over Taxotere; in response, the PACT Manager encourages the rep to highlight, among other things, Taxotere's PACT services. Relator Ex. 119.[17]

Aventis's main response is that the PACT program also had benevolent purposes. *See, e.g.*, Aventis Summ. J. Br., at 23 (ECF No. 303) ("[T]he evidence shows that the intent and effect of the PACT Program was to assist *patients*, its ultimate beneficiaries . . . .). Of course, if the jury credits any of Gohil's evidence that PACT's purpose was, in part, to induce Taxotere prescriptions, then these benevolent purposes would be irrelevant. *See Greber*, 760 F.2d at 72 (3d Cir. 1985) ("If the payments were intended to induce the physician to use the

[17] Along with these emails, Gohil also argues that PACT's structure suggests that it was geared toward increasing sales. Aventis's "reimbursement managers," who oversaw PACT's operation, reported to Aventis's sales and marketing departments, had their bonuses tied in part to sales figures, and received performance reviews that listed "Grow[ing] Current Business" as a "Key Goal." Relator's Ex. 6 (Hayes Dep.) at 33:22-34:1; Ex. 8 (Brown Dep.) at 41:4-13, 99:8-15; Ex. 90 (Brown's performance review). This supports an inference that one of PACT's purposes was to boost sales.

[defendant's] services, the [AKS] was violated, even if the payments were also intended to compensate for professional services."); *Wood*, 246 F. Supp. 3d. at 806 ("[T]o prove a violation of the AKS, one need not prove that the primary or sole purpose of the remuneration was to induce the referral of patients . . .; it is enough if that was 'one purpose' of the remuneration.").

But Aventis also points to deposition testimony from Loreen Brown, a PACT Reimbursement Manager, denying that one of PACT's purposes was to help increase sales. *See* Aventis Ex. I (Brown Dep.) at 465:1-4. While the balance of the evidence favors Gohil on this point, Brown's testimony creates a sufficient factual dispute to make summary judgment inappropriate on this element. *Cf. Justofin v. Metropolitan Life Ins. Co.*, 372 F.3d 517, 524 (3d Cr. 2004) ("The issue of intent is 'particularly inappropriate for resolution by summary judgment' because evaluating state of mind often requires the drawing of inferences from the conduct of the parties about which reasonable persons might differ." (citations omitted)).

3. AKS Scienter.

The third and final element in the AKS analysis is the requirement that a defendant act "knowingly and willfully." 42 U.S.C. § 1320a-7b(b)(2). Here, too, there are sufficient disputes of material fact to render summary judgment inappropriate. The AKS's "knowingly and willfully" standard requires proof that

the defendant "knew [that its] conduct was unlawful and intended to do something that the law forbid." *United States v. Goldman*, 607 F. App'x. 171, 174 (3d Cir. 2015); *see also United States ex rel. Lutz v. Berkeley HeartLab, Inc.*, 2017 WL 4803911, at *3 (D.S.C. Oct. 23, 2017); *Suarez*, 2019 WL 4749967, at *13 (N.D. Ill. Sep. 30, 2019).

The Third Circuit has instructed that "issues of knowledge and intent are particularly inappropriate for resolution by summary judgment." *Riehl v. Travelers Ins. Co.*, 772 F.2d 19, 24 (3d Cir. 1985). Gohil has presented sufficient evidence to survive summary judgment on this issue, including the following:

- During the relevant time period, Aventis received and internally shared several public-news stories describing relevant OIG guidance and warning, in general terms, that some patient-assistance programs may violate the AKS. *See* Relator Exs. 109, 110, 111, 112, 114, & 115.
- In 2000, the OIG issued a public advisory opinion that specifically concluded that a replacement-drug program similar to PACT's violated the AKS. OIG Advisory Op. 00-10, at 7.
- [redacted]

[redacted]

In addition to those pieces of evidence, Gohil also provides strong proof of scienter in the form of two emails from Loreen Brown, Aventis's PACT Reimbursement Manager. In the first, Brown notes that Aventis has a policy against providing replacement drug to doctors who receive any reimbursement. She then adds that this policy may "sound[] like a technicality, but . . . will keep the office from being accused of fraud," because otherwise the doctor would "be receiving too much reimbursement." Relator Ex. 56. In the second email, Brown describes a variant of this policy—that Aventis requires doctors to repay Aventis for replacement drug if they later get reimbursed for a given claim. Relator Ex. 104. Then, however, she writes: "I don't think [Aventis] has ever really enforced this 'rule.'" *Id.* Finally, she observes that some specific doctors—those prescribing Taxotere for prostate, head, and neck uses—"previously received free replacement product from PACT" and may have later received reimbursement, but writes that "I don't think we need to track these physicians down." *Id.*

Together, these two emails support inferences that (1) Brown, an Aventis manager in charge of PACT, knew that it may be illegal to provide replacement

[redacted]

The Court does not rule, at this stage, on whether the document is privileged. But even if the document *is* privileged and inadmissible, the rest of the evidence in the record would still create a genuine dispute of material fact on AKS scienter.

drug to doctors who also receive reimbursement; (2) Brown knew Aventis did not enforce an internal policy aimed at preventing just that type of double-payment; and (3) Brown knew of specific doctors who may have received both reimbursement and replacement drug, but said that there was no need to enforce the policy against those doctors. These inferences would surely support a finding of AKS scienter.

In response, Aventis contends that it took compliance seriously and implemented internal policies to ensure that PACT complied with federal and local laws. *See, e.g.*, Aventis Ex. HH (Scelfo Dep.) at 61:25-62:13 (PACT Reimbursement Manager stating that PACT employees worked closely with legal teams to comply with all laws); Exs. ZZ & YY (Aventis contracts requiring that its third-party PACT vendors comply with all laws, including AKS). While the two Brown emails discussed immediately above suggest that Aventis did not always enforce its policies, that is a question that the jury can ultimately resolve.

Aventis also argues [redacted] that the communications that Relator points to (i.e., Exhibits 109-115) do not show that Aventis had any culpable mental state. But the "effect that various communications had on [Aventis's] scienter is a factual inquiry that must be submitted to the jury." *Berkeley HeartLab*, 2017 WL 4803911, at *4 n.2 (D.S.C. Oct. 23, 2017). Accordingly, summary judgment is inappropriate for this element.

4. Conclusion on AKS and FCA-Falsity

As a reminder, the FCA has four elements: (1) falsity; (2) causation; (3) knowledge; and (4) materiality. In this case, the "falsity" analysis turns entirely on whether Gohil can prove that PACT violated the AKS. Based on the evidence in the record, a reasonable jury could certainly conclude that (1) the PACT's replacement-drug feature was "remuneration" because it worked as a functional reimbursement guarantee; (2) at least one purpose of PACT was to increase Taxotere prescriptions; and (3) Aventis behaved "knowingly and willfully" because it (a) knew that replacement-drug features like PACT's implicated the AKS and (b) knew that it sometimes overcompensated doctors by not requiring them to repay Aventis for replacement-drug if they were later reimbursed.

On the other hand, however, Aventis creates factual disputes as to each of these elements. First, as to remuneration, Aventis points to testimony that its sales representatives were not allowed to use PACT's replacement-drug feature as a reimbursement guarantee. Second, as to the "one purpose" element, Aventis points to Loreen Brown testimony denying that PACT was meant to increase sales. Finally, as to the AKS scienter standard, Aventis disputes the weight of the [redacted] and other communications Gohil cites, and argues that its internal policies demonstrate *compliance* with—not knowing violation of—the law.

Because there are disputes of material fact as to whether PACT violated the AKS, that means that there is a genuine dispute of material fact as to whether Gohil can satisfy the FCA's "falsity" element. Next, the Court turns to the other three FCA elements: causation, FCA scienter, and materiality.

B. Causation

The next FCA element is causation. To satisfy this element at the summary judgment stage, Gohil must "prove that at least one" claim "sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute." *Greenfield*, 880 F.3d at 98 (3d Cir. 2018). In other words, Gohil may not simply describe the PACT scheme in the abstract—he must also "link" that scheme to a "particular claim" submitted to the government for payment. *Id.* at 98, 100.[19]

If Gohil can prove that PACT violated the AKS, he can easily satisfy this second element, and Aventis does not appear to dispute it. Gohil points to several specific claims for reimbursement submitted to the Government through PACT's appeal process, which is sufficient to satisfy *Greenfield*'s requirement of a link between this kickback theory and an "actual claim." *See* Relator Ex. 88 (pointing to several such claims).

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[19] *See also id.* at 98 ("A plaintiff cannot 'merely . . . describe a private scheme in detail but then . . . allege . . . that claims requesting illegal payment must have been submitted, were likely submitted[,] or should have been submitted to the Government. Instead, he must provide 'evidence of the actual submission of a false claim' to prevail at summary judgment." (citations omitted)).

C. FCA Scienter – "Knowledge"

The FCA only applies to defendants who behave "knowingly." 31 U.S.C. §§ 3729(a)(1) & (2). The statute defines "knowing" or "knowingly" to mean that a person "has actual knowledge of the information" in question or acts in "deliberate ignorance" or "reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b).[20] The term does not require "proof of specific intent to defraud." *Id.* In legal falsity cases—where the "falsehood" in question is a violation of an underlying law, regulation, or contractual requirement—this scienter element essentially requires deliberate ignorance or reckless disregard of illegality.

As previously explained, there are disputes of material fact as to the AKS's scienter element—which is part of the falsity analysis. The AKS's scienter element is harder to meet than the FCA's scienter standard—the AKS requires that a defendant have *knowledge* of illegality, whereas the FCA requires only recklessness or deliberate ignorance of illegality. Therefore, because Gohil can survive summary judgment as to the AKS's scienter requirement, he can also survive summary judgment on the FCA's scienter element. The evidence that creates disputes of material fact as to the AKS's scienter element does the same

[20] The Court uses the pre-2009 codification of the FCA's definition of "knowingly." After 2009, the codification of this definition changed slightly, but its substance stayed the same.

thing for the FCA's easier-to-satisfy standard.

D. Materiality

The fourth and final element of an FCA cause of action is materiality. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). A "misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Id.* at 1996. "Material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 761 (3d Cir. 2017) (internal quotation marks omitted).[21]

It is possible for a claim to be "legally false" but still fail to satisfy the materiality requirement, because "falsity and materiality are distinct requirements," *Greenfield*, 880 F.3d at 98 n.8. For instance, if Congress passed a law that government contractors could not be paid unless they only used American-made staplers, and a given contractor failed to disclose that its office used a single

[21] In 2009, Congress amended the FCA to provide a uniform definition of materiality, which *Spay* quotes here. After 2009, this definition is now codified at 31 U.S.C. § 3729(b)(4). But the Third Circuit has made clear that the amendment "did not inject a new materiality standard into the FCA. Rather, the changes merely made explicit and consistent that which had previously been a judicially-imposed, and oftentimes conflicting, standard." *Spay*, 875 F.3d at 761. Thus, "the definition of 'material,' which is derived from common law and was enshrined in the statute itself in 2009, has not changed." *Id.* at 763.

Canadian-made stapler, that may well satisfy the "legal falsity" requirement. But the violation may fail the "materiality" requirement if it was so insubstantial that the government would have paid the contractor even if it knew of the violation. *Escobar*, 136 S. Ct. at 2004. This outcome—and the "demanding" materiality standard—stem from the recognition that the FCA is "not 'an all-purpose anti-fraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 2003 (citation omitted).

In *Escobar*, the Supreme Court "clarif[ied] how [the] materiality requirement should be enforced," articulating several factors that a court should consider. *Id*. at 2002. To start, a "misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." *Id*. at 2003. The government's "decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* Likewise, a condition of payment is not material merely because the Government has the "option to decline to pay if it knew of the defendant's noncompliance," nor will materiality exist if "noncompliance is minor or insubstantial." *Id.*; *see also id.* at 2003 n.5 ("[A] misrepresentation is material if it 'went to the very essence of the bargain.'" (quoting *Junius Constr. Co. v. Cohen*, 178 N.E. 672, 674 (N.Y. 1931))).

Proof of materiality "can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* at 2003. On the other hand, "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements were not material." *Id.* at 2003-04. The same point applies if "the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position." *Id.* at 2004.

Here, the parties raise a threshold legal dispute. Gohil argues that AKS violations are *per se* material under the FCA. Aventis disagrees. The vast majority of courts to address this question after *Escobar* have agreed with Relator that AKS violations are *per se* material.[22] But on the other hand, in *Greenfield*, an

[22] For cases concluding that AKS violations are *per se* material, *see Guilfoile v. Shields*, 913 F.3d 178, 190-91 (1st Cir. 2019); *United States v. Medoc Health Servs., LLC*, --- F. Supp. 3d ----, 2020 WL 3892453, at *9 (N.D. Tex. July 2, 2020); *United States ex rel. Strunck v. Mallinckrodt ARD LLC*, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020); *United States ex rel. Longo v. Wheeling Hosp., Inc.*, 2019 WL 4478843, at *8-*10 (N.D. W. Va. Sep. 18, 2019); *Capshaw v. White*, 2018 WL 6068806, at *4 (N.D. Tex. Nov. 20, 2018); *United States ex rel. Lutz v. Berkeley HeartLab, Inc.*, 2017 WL 6015574, at *2 (D.S.C. Dec. 4, 2017); *see also United States ex rel. Arnstein v. Teva Pharms. USA, Inc.*, 2019 WL 1245656, at *28-*29 (S.D.N.Y. Feb. 27, 2019) (claims tainted by AKS violations are *per se* material if submitted after 2010, but are not *per se* material if submitted prior to

AKS-FCA case, the Third Circuit wrote in dicta that even if a relator proves an AKS violation, satisfying the FCA's "falsity" element, "he must *also satisfy* the False Claims Act's materiality requirement, *as falsity and materiality are distinct requirements in this context*." 880 F.3d at 98 n.8 (emphasis added).

Whether or not AKS violations are *per se* material, however, summary judgment would remain inappropriate. If AKS violations are *per se* material, there would still be disputes of material fact as to whether PACT violates the AKS in the first place. But even if AKS violations are not *per se* material under the FCA, a jury could find materiality on the record and arguments presented here.

Escobar "makes clear that courts are to conduct a holistic approach to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive." *United States ex rel. Escobar v. United Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016). *Escobar*'s discussion of materiality can be distilled into the following factors: (1) whether compliance with a particular statute is a "condition of payment," (2) whether the violation goes to "the essence of the bargain" or is "minor or insubstantial," and (3) whether the government pays or declines to pay similar claims when it has "actual knowledge" that the claims are tainted by the same kind of violation. *See Berkeley HeartLab*, 2017 WL

2010). *But see United States ex rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392, 416 (D.N.J. 2019) (concluding, in FCA-AKS summary judgment opinion, that materiality was "a question . . . that must be answered by a jury in this case.").

6015574 at *2 (summarizing the factors discussed in *Escobar*); *United States ex rel. Emanuele v. Medicor Assocs.*, 242 F. Supp. 3d 409, 431 (W.D. Pa. 2017) (same); *Escobar* at 2003-04. In addition, because *Escobar* deemed the criteria it discussed to be non-exclusive, a fourth category may include any other indications of materiality. Here, that fourth category consists of arguments both sides make related to government enforcement actions in AKS cases.

1. Compliance With the AKS is A Condition of Payment.

The first factor weighs in favor of finding materiality because "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare." *Wilkins*, 659 F.3d at 313 (3d Cir. 2011). As *Escobar* explicitly points out, although this factor may not be "automatically dispositive" to materiality, it is certainly "relevant" to the inquiry. *Escobar*, 136 S. Ct. at 2003.

2. AKS Violations Are Serious and Substantial.

The second factor—whether the violation is "insubstantial" or goes to the "essence of the bargain"—also favors a finding of materiality. AKS violations are "not [the] 'garden-variety breaches of contract or regulatory violations' that the Supreme Court sought to shield from the wrath of the FCA." *Capshaw*, 2018 WL 6068806, at *4 (N.D. Tex. Nov. 20, 2018) (quoting *Escobar* at 2003). They are serious criminal felonies punishable—during the relevant time-period in this

case—by up to five years in prison,[23] and the "Government routinely punishes AKS violations through criminal proceedings and civil proceedings to recoup funds." *Berkeley HeartLab*, 2017 WL 6015574, at *2.

Further, mirroring the "essence of the bargain" language used in *Escobar*, the Third Circuit has explicitly recognized that "the Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback." *Wilkins*, 659 F.3d at 314. In short, a "violation of the AKS is a far cry from an 'insubstantial' regulatory violation like, say, requiring 'that . . . contractors buy American-made staplers' rather than foreign staplers." *Wood*, 246 F. Supp. 3d at 818 (S.D.N.Y. 2017) (citation omitted).

3. Evidence as to Prior Payment or Refusal to Pay Claims With Similar Violations.

Neither side makes a strong argument under the third factor—the government's payment or denial of claims when it has "actual knowledge" of similar violations—because neither side presents any evidence of prior payment decisions where the Government had actual knowledge of an AKS violation. Gohil does not attempt to do so. Aventis does, but the evidence it cites is not persuasive.

[23] In 2018, Congress increased the maximum incarceration term for AKS violations from five to ten years. *See* Bipartisan Budget Act of 2018, Pub. L. No. 115-123, § 50412(b)(2), 132 Stat. 64, 221 (2018).

Aventis points out that Medicare officials paid reimbursement claims for Taxotere while aware that PACT employees were involved in the reimbursement process. Specifically, Aventis notes that PACT officials authored appeal letters that identified themselves by their position with PACT/Aventis. *See* Aventis Ex. NNN (PACT's model appeal letters, all of which contain signature blocks making clear that the letter's author worked for PACT and Aventis); Aventis Ex. HHHH (internal document referring to various communications between PACT employees and Medicare officials regarding claim appeals). While this evidence may show that the government knew, at times, that PACT officials were involved in the claims process, it does not demonstrate the awareness of an actual AKS violation. For instance, nothing in these exhibits shows any awareness by the Government that PACT offered replacement-drug to physicians whose claim appeals failed, nor do they show any awareness that PACT would sometimes (allegedly) market the replacement-drug feature to doctors as a reimbursement guarantee. Likewise, the exhibits do not reveal an awareness that PACT services were offered for free. Accordingly, Aventis's evidence does not show that the Government paid claims with "actual knowledge" of an AKS violation.

In addition, Aventis argues that the Government has been aware of Gohil's allegations for seventeen years, yet during that time, it has consistently paid reimbursement claims for Taxotere. This argument suffers from a similar flaw:

awareness of allegations does not equate to "actual knowledge" of a violation. *See Berkeley HeartLab, Inc.*, 2017 WL 4803911, at *7 (noting that it may take years for the Government to investigate a relator's allegations, and that the "Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing"); *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) ("[M]ere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance."); *Teva*, 2019 WL 1245656, at *33 ("[E]vidence of the . . . disclosure of [Relators'] complaint, combined with evidence of continued payment, is insufficient to warrant granting summary judgment to Defendants [on materiality grounds]."); *United States ex rel. Brown v. Pfizer, Inc.*, 2017 WL 1344365, at *11 (E.D. Pa. Apr. 12, 2017) ("The mere fact that the government has continued to pay and approve claims . . . even after Relators' allegations in 2005 is insufficient to establish that Relators' claims lack materiality.").

4. Evidence and Arguments Regarding Government Enforcement Practices.

While neither side points to any compelling evidence as to the government's payment practices when it knew of AKS violations, both sides raise related arguments focused on the government's *enforcement* of AKS violations.

Enforcement decisions and payment decisions do not line up perfectly. They are made by different government officials and involve different considerations. Payment decisions are made by employees of the Centers for Medicare & Medicaid Services ("CMS"), while enforcement decisions are made by the DOJ and OIG's offices.[24] And enforcement decisions involve a myriad of considerations (e.g., deterrence and retribution, allocation of limited investigative resources, competency of private *qui tam* relators, development of precedent for future actions) that may not be present in payment decisions. Nonetheless enforcement decisions may still have some relevance to *Escobar*'s holistic materiality analysis—for instance, if evidence exists that the government has never enforced violations of a given statute, that may be relevant to determining whether it is the sort of "garden-variety" violation that fails the materiality element. *Cf. Teva*, 2019 WL 1245656, at *31 ("While [evidence of prior enforcement actions] does not demonstrate that the Government 'consistently refuses to pay claims' based on AKS violations like the ones at issue here, other district courts have

[24] *Accord* Gov't Statement of Interest, at 4 (ECF No. 410) ("Aventis does not argue . . . that CMS had actual knowledge that Aventis [violated the AKS] when CMS paid Taxotere claims. . . . Instead, Aventis argues that the government's *investigative* team—i.e., [DOJ] attorneys and agents from the Department of Health and Human Services' Office of Inspector General ("HHS-OIG")—had the requisite 'actual knowledge' of Aventis's misconduct. . . . [But] federal healthcare programs make payment decisions, not DOJ attorneys or HHS-OIG agents. . . . [E]ffort[s] to conflate CMS (the payment agency) and DOJ and HHS-OIG (the investigating agencies) [are] misleading and should be unavailing.").

found that [this evidence] weighs slightly in favor of a finding of materiality under the FCA. . . . [T]his Court [thus] assigns some probative value to [this kind of evidence].” (citations and internal brackets and quotation marks omitted)).

Gohil points out that the government frequently initiates FCA enforcement actions to *recover* money paid on AKS-tainted claims for reimbursement. *See, e.g.*, Relator Ex. 106b (October 3, 2001 press release announcing government settlement with defendant accused of FCA-AKS violations); Ex. 107 (government statement of interest in 2002 FCA-AKS case arguing that AKS violations are material); *see also Berkeley HeartLab*, 2017 WL 6015574, at * 2 (noting that “the Government routinely punishes AKS violations through criminal proceedings and civil proceedings to recoup funds,” and collecting cases); *Wood*, 246 F. Supp. 3d at 818 (same). As noted above, this has some slight probative value that weighs in favor of materiality.

Aventis responds with its own enforcement-related arguments, highlighting the fact that the government has been aware of Gohil’s allegations since 2002 but has repeatedly declined to intervene in this action. This may be of some relevance, though it surely does not warrant granting summary judgment in Aventis’s favor. *See Petratos*, 855 F.3d at 490 (3d Cir. 2017) (noting that relator failed to adequately allege materiality and adding that “in th[e] six years” since relator disclosed evidence of the defendant’s alleged misbehavior, “the Department of

Justice has taken no action against [defendant] and has declined to intervene in this suit")[25]; *Polansky v. Exec. Health Res., Inc.*, 422 F. Supp. 3d 916, 938-39 (E.D. Pa. 2019) (Baylson, J.) (finding the government's declination to intervene in FCA case probative of materiality); *Cressman v. Solid Waste Servs., Inc.*, 2018 WL 1693349, at *6 (E.D. Pa. Apr. 6, 2018) (Quiñones Alejandro, J.) (same).

Aventis also points out that in 2000, the OIG issued an advisory opinion in which it declined to seek civil enforcement sanctions against a pharmaceutical company that used a replacement-drug feature similar to PACT's. *See* OIG Advisory Op. 00-10, at 7-8 (finding that the replacement-drug program "implicates the [AKS] . . . [by] confer[ring] an independent financial benefit" to doctors, but declining to pursue sanctions, emphasizing that the program had sufficient

[25] In *Petratos*—which dealt with a motion to dismiss—the Third Circuit held that the relator failed to allege materiality because he "concede[d] that CMS would *consistently reimburse* [claims tainted by the alleged violation] with full knowledge of the purported noncompliance." *Id.* at 490. In light of this clear deficiency, which formed the basis of the Court's dismissal, it is clear that the Government's decision not to intervene, while perhaps relevant, was not the dispositive consideration. *Petratos* indicates that declination to intervene is of *some* relevance to materiality. Nonetheless, its probative value is low.

Indeed, providing too much weight to the government's decision not to intervene would undermine the private-enforcement structure at the heart of the FCA. *Cf. United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 836 (6th Cir. 2018) ("If relators' ability to plead sufficiently the element of materiality were stymied by the government's choice not to intervene, this would undermine the purposes of the [FCA,] . . . [which] is structured such that it encourages private citizens to enforce actions on behalf of the government.").

safeguards in place to prevent abuse and overutilization). This, too, is relevant to materiality but not dispositive. For instance, while Aventis argues that PACT's replacement-drug program had safeguards similar to those in the 2000 OIG Opinion, Gohil has submitted evidence that Aventis did not always follow these safeguards, which creates a factual dispute for a jury to resolve.

In short, there are sufficient disputes of fact as to materiality to preclude granting summary judgment in either party's favor on this element at this stage.

IV. Conclusion

For the reasons above, neither Gohil nor Aventis are entitled to summary judgment on the question of whether Aventis's PACT Program violated the Anti-Kickback Statute and False Claims Act. Accordingly, I denied both cross-motions for summary judgment.

s/ ANITA B. BRODY, J.
ANITA B. BRODY, J.

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